UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,785	09/12/2003	Joern Moeckel	2924-216	5867

6449 7590 10/24/2007

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/660,785	MOECKEL ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-21-2007 has been entered.

Claims 21 – 35 and 37 – 41are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 – 35, and 37 – 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claims 21, 40 and 41 recite, in pertinent part, ". . . .wherein when a coating is used which does not dissolve during contact with the digestive solution in a patient's stomach, a pore forming agent is included with the coating to separate the coating from

the core during contact with the digestive solution in the patient's stomach." This recitation is new matter which is not supported by the originally filed disclosure. The originally filed disclosure does not contain this proviso.

The remaining claims are rejected for ultimately depending on one of the abovementioned claims, thus incorporating the new matter thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 21 – 35 and 37 – 41 rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,149,052 in view of EP 0 421 921 and Canadian Pat. 1,305,166 is **withdrawn**.

Applicants' argument is persuasive. The prior art recognizes that cellulose acetate phthalate is an enteric polymer, and thus will not dissolve in the stomach of a patient. Accordingly, it cannot be concluded that the cellulose acetate phthalate coated composition suggested by the art would release 30% or more of the active agent in the stomach.

Claim Rejections - 35 USC § 112

Claims 21 – 35 and 37 – 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant Application, the artisan would not be able to practice the method step of the invention requiring "wherein at least 30% of the administered amount of the ibandronate is released . . . into the stomach. . ."

Enablement is lacking when a person of ordinary skill in the art would require undue experimentation to practice the invention. Undue experimentation may be determined in view of the factors enumerated in MPEP 2164.01(a). All of these factors have been considered, and the most pertinent are discussed below.

The nature of the invention and scope of the claims: The invention relates to the drug ibandronate. In order to release the drug into the stomach without causing injury or irritation to the esophagus, the inventors propose using dosage forms coated with either coatings that dissolve in the stomach or with enteric polymers to which pore formers are added. The instant claims are limited to a specific set of coating polymers, all of which are enteric polymers (see USP 28/NF 23 2005, Felton et al., Moustafine et al., and Guo et al., cited on PTO 892 as evidence of this assertion), so the first aspect of the invention of no concern here. By way explanation, enteric polymers have the property of being insoluble in the pH of the stomach but soluble in the pH of the intestine. See Felton et al.

The state of the prior art: The prior art recognizes the use of enteric coated tablets in combination with pore formers. See US 2006/0045865, cited on PTO 892, particularly paragraphs [0070] and [0071]. In the prior art, such coatings are used for delayed release of drugs into the small intestine, with a delay time of three hours or

more. Park et al. (cited on PTO 892) show that tablets which do not dissolve in the stomach clear the stomach and enter the small intestine in about 2 hours or less in humans and in animal models (see page 211). This supports the notion that a delayed release time of 3 hours or more in fact means release of the drug in the small intestine but not in the stomach.

The level of predictability in the art: The art is unpredictable *vis a vis* the claimed "wherein at least 30% of the administered amount of the ibandronate is released . . . into the stomach. . ." The art strongly suggests to the artisan that the combination of an enteric polymer and a pore former used as a coating for a drug core would in fact release the drug in the small intestine. Accordingly, the art clearly suggests that the combination of pore former and enteric coating would not predictably release 30% or more of a drug in the stomach.

The amount of direction provided by the inventor and the existence of working examples: The inventor provides little direction with respect to the combination of pore former and enteric coating. The examples do not deal with this type of coating; Examples 1 – 3 use an HPMC coating, Example 5 uses a saccharose based coating, Example 6 uses a gelatin capsule, and example 7 uses a lactose/microcrystalline cellulose coating. Example 4 uses an enteric coating methylhydroxypropylcellulose phthalate, but does not use a pore former. The remaining components of the coating are the plasticizer triacetin and the surfactant polysorbate. Further, there is no showing that this Example is useable in the claimed method (i.e. that upon ingestion it would release more than 30% of its drug in the stomach).

Recognizing that enablement need not come from the examples, but that the entire specification must be taken into account, it is noted that the use of gastric juice-resistant films (likely corresponding to enteric polymers) is discussed on the first paragraph of page 7 of the specification. This discussion lists the types of enteric polymers that may be used, and also states that if such polymers are used, that they should be used in "thin layer thickness of the coating or. . . extremely high percentage of pore-forming agents or the like." However, nowhere in the specification is the artisan informed of what percentage of pore-forming agents is effective, or "extremely high". Further, the disclosure does not inform the artisan what pore-formers are appropriate to give the desired effects. Nor does the disclosure discuss what thicknesses correspond to "thin layer thickness of the coating" that would achieve the claimed effect.

The quantity of experimentation needed to practice the invention based on the contents of the disclosure: In order to practice the invention, the artisan would essentially have to start from scratch in determining what pore formers to use, in what concentration to use them, and with which polymers may any given pore former be used, in order to produce the desired effect. This in effect would be a pseudo-assay, where the artisan would be trying random "shot in the dark" guesswork, hoping to find a solution. Given the disclosure of the prior art, the artisan would not expect to succeed.

The required trial and error, guesswork type experimentation needed by the artisan to practice the invention is clearly undue. The proper determination is that the instant claims are not enabled by the specification.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600